MAY - 4 2001

K003442 p1/2

510(k) Summary
for the MODIFIED VERIS System
Prepared March 25, 2001

Company Name: Electro-Diagnostic Imaging, Inc.
1206-D West Hillsdale Blvd.
San Mateo, California 94403
Telephone 650 341 5054

Contact Person: Erich E. Sutter Ph.D.

A. Legally Marketed Predicate Device

The MODIFIED VERIS System is substantially equivalent to the EDI VERIS System ((K983983).

B. Device Description

Photic stimuli are presented to the patient on a CRT screen up to 60 degrees at 241 elements in separately stimulated fields. Various modes are available for preferential stimulation of different retinal mechanisms and isolation of signal from different retinal layers. Data is acquired by 2 recording channels using conventional EEG electrodes. During the period of time that the system is acquiring data (4-16 minutes), there is a real time display of the raw and processed data presented to the user. Once the resulting individual waveforms are acquired, the signals are analyzed by software using algorithms for spatial filtering and artifact rejection. Data may be presented in a number of forms, including waves recorded at each of the points tested, color plots, or 3D topographical representations.

C. Intended Use

The MODIFIED VERIS system is an electrodiagnostic device used to generate photic signals and to measure and display the electrical signals generated by the retina and the visual nervous system. It displays digitized electroretinogram (ERG) and visual evoked potential (VEP) signals, power spectra and topographic maps. These functions are controlled and interpreted by trained medical professionals.

D. Substantial Equivalence

	Predicate Device	Submission Device	Substantially Equivalent
Product Name	VERIS ERG System (K983983)	MODIFIED VERIS ERG System	
Intended Use	Generate photic signals and measure and display the electrical response signals generated by the retina and the visual nervous system	Generate photic signals and measure and display the electrical response signals generated by the retina and the visual nervous system	Yes
Intended Users	Ophthalmologists and trained medical technicians	Ophthalmologists and trained medical technicians	Yes
Indications for Use	Diagnosis and management of retinal ischemic diseases, diabetic retinopathy, central or branch vein occlusion	Diagnosis and management of retinal ischemic diseases, diabetic retinopathy, central or branch vein occlusion	Yes
Intended Population	Patients with ophthalmic conditions	Patients with ophthalmic conditions	Yes
Site of Use	Hospital, clinics and physician offices	Hospital, clinics and physician offices	Yes
Data Collected	ERG waveforms	ERG waveforms	Yes

E. Performance Data

The MODIFIED VERIS System has been tested for electrical safety and has received a certificate of compliance with EN60601-1-2:1993 and EN55011:1991 Standards.

Safety

The 7" stimulator is equivalent to the 21" monitor in regard to safety and complies with IEC 601-1-2.

The 1.5" stimulator is equivalent to the 21" monitor in regard to safety and complies with IEC 601-1-2. When the 15" unit is used in combination the IR projectors or the IR emitting electrode, the patient's eye is exposed to a low level of IR radiation. The level of exposure was measured and represents no risk to the patient.

Effectiveness

All three monitors (21", 7" and 1.5") provide equivalent stimulation for the purpose of evoked potential (ERG, VEP) recording in all regards (stimulus luminance, chromaticity and size of the stimulated visual field). The newly introduced 7" and 1.5" stimulator units however, offer the following additional advantages:

7" stimulation unit

The light weight (ca. 15 lb) of the unit permits mounting on an articulating arm for easy positioning in front of the patient's eye and alignment with the contact lens electrode used for ERG recording. This facilitates operation, permits more comfortable patient positioning and thus results in less noise contamination of the recorded signals and better quality data.

1.5" unit with fundus monitoring

This option permits monitoring the position of the stimulus array on the fundus of the eye during recording. It is an important quality control, particularly with AMD patients who have little or no central vision. The entire unit weighs less than 7 lb and thus offers the same advantages as the 7" unit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Electro-Dianostic Imaging, Inc.
c/o Sheila W. Pickering Ph.D.
Regulatory Affairs Consultant
2081 Longden Circle
Los Altos, CA 94024

Re: K003442
Trade Name: VERIS™ System
Regulatory Class: II
Product Code: 86 HLX and HLZ
Regulation: 886.1630 and 886.1220
Dated: March 30, 2001
Received: April 3, 2001

Dear Dr. Pickering:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K003442

Device Name: VERIS™ System

Indications For Use:

The VERIS System is an electrodiagnostic device used to generate photic signals and to measure and display the electrical signals generated by the retina and the visual nervous system. It displays digitized electroretinogram (ERG) and visual evoked potential (VEP) signals, power spectra, and functional topographic maps. It is available with an optional corneal electrode which has an IR light source for illuminating the fundus. These functions are controlled and interpreted by trained medical professionals. The device is intended for use to aid in the diagnosis and management of retinal ischemic diseases, diabetic retinopathy, and central or branch vein occlusion.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003442

(Optional Format 3-10-98)